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(71) Applicant *(for all designated States except US)*: **JOHNSON & JOHNSON CONSUMER FRANCE S.A.S.** [FR/FR]; 1, rue Camille Desmoulins, F-92787 Issy-les-Moulineaux, Cedex 9 (FR).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **MORELLI, Muriel** [FR/FR]; 55, rue du Moulin Potel, F-27400 Acquiny (FR). **JOUSSELIN, Magali** [FR/FR]; 18, Residence Les Jardins des Matrais, F-27430 Saint-Pierre du Vauvray (FR).

(74) Agent: **WANTE, Dirk**; Johnson & Johnson NCB, European Patent Group, Lenneke Marelaan 6, B-1932 Sint-Stevens-Woluwe (BE).

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(54) Title: COMPOSITIONS OF POLYMERIZED WHEAT PROTEINS AND ETHANOLAMINE DERIVATIVES

(57) Abstract: This invention relates to compositions comprising an ethanolamine derivative and a polymerized wheat protein. It further relates to the use of such compositions in topical formulations, in particular in anti-aging formulations. The invention further relates to the use of such compositions to combat the effects of skin aging.

# Compositions of Polymerized Wheat Proteins and Ethanolamine Derivatives

## Brief description of the invention

This invention relates to compositions comprising an ethanolamine derivative and a polymerized wheat protein. It further relates to the use of such compositions in topical formulations, in particular in anti-aging formulations. The invention further relates to the use of such compositions to combat the effects of skin aging.

## Background of the Invention

The appearance and condition of the skin may be degraded through external factors such as sunlight, exposure to wind and to cool and dry air, air pollutants, smoking, as well as internal factors such as dermatological diseases, age-related hormonal changes, or the normal aging process.

As a first sign of aging, skin becomes less elastic and develops fine lines and wrinkles, which are the direct result of deterioration of the supporting dermis layer. In fact the skin's ability to replace damaged collagen diminishes and more and more disconnections and irregularities develop in the collagen network. Further phenomena associated with skin aging are the appearance of pigment marks, skin thinning and skin sagging.

Cosmetic products have been developed that have proved out to be more or less effective in combating the effects of skin aging. Particular such products are those containing vitamins or vitamin derivatives, in particular vitamin A or its derivatives (retinoids), vitamin C, alpha-hydroxy acids or plant extracts. These products, when applied regularly during longer periods of time, have been shown to reduce the number of wrinkles and fine wrinkles. A particular pathway used in the treatment of the effects

of skin aging is by stimulation of dermal human fibroblasts and collagen formation. Agents possessing these properties for example are L-ascorbic acid and in particular retinol.

Other agents that have been described as useful to treat the effects of skin aging are the ethanolamine derivatives. US 5,554,647 describes a method of treating aging skin and subcutaneous muscles comprising the use of an acetylcholine precursor such as dimethylaminoethanol (DMAE) in an amount effective to produce increased muscle tone.

US 5,643,586 describes the topical treatment of subcutaneous muscle and overlying cutaneous tissue by applying a composition comprising a catecholamine precursor which in particular is tyrosine, phenylalanine or a mixture thereof preferably in combination with an acetylcholine precursor such as dimethylaminoethanol.

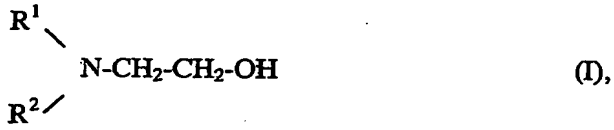
EP-A-1219288 relates to a topical composition for the treatment of skin, in particular to improve skin firmness, comprising an effective amount of an ethanolamine salt which has a mixture of anionic counterions derived from at least two pharmaceutically acceptable acids and esters thereof; and a cosmetically acceptable carrier. This reference teaches that the ethanolamines as disclosed therein affect the biomechanical properties of the skin thus restoring youthful firmness resulting in improved facial contours.

Although these methods and the products used therein have been applied with varying degrees of success, there nevertheless remains room for improvement. In particular there still is a need for new formulations that are more effective in combating the effects of the skin aging process.

The compositions and formulations according to the present invention, which will be described hereinafter in more detail, are aimed at being effective tools in combating the effects of skin aging.

## Summary of the invention

In a first aspect, the present invention is directed to a composition comprising at least one ethanolamine derivative of formula (I), or a skin acceptable salt thereof:



(I),

and at least one polymerized wheat protein.

In formula (I) $R^1$ and $R^2$ independently represent hydrogen, $C_{3-6}$ cycloalkyl or $C_{1-6}$ alkyl, optionally substituted with hydroxy, methoxy, oxo or formyl.

Preferably $R^1$ and $R^2$ independently represent $C_{1-4}$ alkyl.

The most preferred ethanolamine of formula (I) is dimethylaminoethanol (DMAE), also referred to as deanol.

The polymerized wheat protein is obtainable from hydrolyzed wheat protein hydrolysates, which are polymerized by using an appropriate multifunctional polymerizing agent.

The invention further is concerned with a topical formulation comprising a composition as defined herein and a cosmetically-acceptable or dermatologically-acceptable topical carrier. The latter may comprise one or more further ingredients. The topical formulation can be for dermatological use but is in particular for cosmetic use.

In another aspect the invention provides the use of a composition as defined herein for manufacturing a topical or in particular a cosmetic formulation. The topical or cosmetic formulations are useful for combating or treating the effects of skin aging.

In a further aspect, the invention provides the use, and more specifically the cosmetic use, of a composition as defined herein, or of a topical formulation as defined herein, for combating or treating the effects associated with the aging of skin.

Or, alternatively, the invention concerns a method, and in particular a cosmetic method, of combating or treating the effects of skin aging, which method or cosmetic method comprises applying to the affected skin area an amount of a composition or of a topical formulation as defined herein, said amount being effective to treat said effects of skin aging.

Still another aspect of this invention comprises a cosmetic method for the improvement of the external appearance of an individual, said method comprising applying an effective amount of a composition or a topical composition as defined herein to affected skin areas.

## Detailed description of the invention

As used herein, any percentage is weight-by-weight (w/w) relative to the total weight of the composition or of the formulation.

As further used herein, 'effective amount' means an amount of composition or formulation sufficient to significantly induce a positive modification in the condition to be regulated or treated, but low enough to avoid serious side effects. The effective amount of the composition or formulation will vary with the particular condition being treated, the age and physical condition of the end user, the severity of the condition being treated/prevented, the duration of the treatment, the nature of concurrent therapy, the specific composition or formulation employed, the particular cosmetically-acceptable topical carrier utilized, and like factors.

The compositions of this invention comprise polymerized wheat proteins of high molecular weight. These polymerized wheat proteins can be prepared by a process comprising the following steps :

1) solubilizing in an aqueous phase a material which is rich in wheat proteins;
2) hydrolyzing by enzymatic reaction in a controlled and limited manner the solution of 1) wherein the level of enzymatic hydrolysis is selected such that monomeric proteins with a molar mass between 20,000 Da and 300,000 Da are obtained;
3) separating the soluble phases from the insoluble phases;
4) polymerizing the proteins by adding a suitable polymerizing agent.

The source of wheat proteins used in the first step can be any material derived from wheat that is sufficiently rich in wheat proteins. Suitable materials are, for example, wheat flour, wheat extracts, wheat gluten and the like.

The process preferably is conducted under following circumstances. The starting wheat protein rich material is solubilized at a concentration of 50 g/l to 500 g/l. Subsequently, the hydrolysis is carried out preferably in acid pH, preferably at a pH level in the range between 4 and 7 and at a temperature between 40°C and 80°C. The enzymes that can be used in the hydrolysis step are proteases of the following type: endoproteases, exoproteases, exopeptidases, proteasepeptidases, aminomeptidases or carbopeptidases, or a mixture of these enzymes. After completion of the reaction the enzymes are inactivated, for example by increasing the temperature of the reaction mixture to a temperature between 50°C and 80°C. The level of hydrolysis is selected such that the percentage of hydrolysed wheat protein in fractions F2 and F3 is between about 70 : 60 to about 50 : 40 and in particular is about 50 : 50 (+/- 5%), with no or almost no hydrolysed protein in fraction F1 (preferably less than about 5%), wherein F1, F2 and F3 are as defined hereinafter.

The polymerizing agent preferably is a multifunctional polymerizing agent selected from the group of polymerization initiators comprising polychlorides of acids, acid polyanhydrides, polyisocyanates, polythioisocyanates. The polymerization step is preferably carried out with a level of polymerization agent between 10 g/l and 100 g/l, selected so as to obtain a level of polymerized proteins that is higher than 30%. Preferably about one equivalent of the polymerizing agent is used.

The separation of the polymerized wheat proteins can be carried out by filtration, decantation, centrifugation and concentration.

Particular polymerized wheat proteins as well as processes for their manufacture have been described in WO-03/040216, which is incorporated herein by reference.

The polymerized wheat proteins are characterized in that they contain

- an amount of dry material, when obtained by heating the isolated polymerized protein at about 105°C until a constant weight is reached, of about 5 g/l to about 500 g/l, preferably of about 50 g/l to about 250 g/l;
- a pH, measured potentiometrically at room temperature, of about 2 to about 10, preferably of about 4 to about 10, more preferably of about 7 to about 8;
- a level of proteins, when measured with the Biuret method at 540 nm, of about 40 g/l to about 400 g/l, preferably of about 40 g/l to about 200 g/l;
- the size distribution of the proteins is defined by their chromatographic profile; the molar mass of the different molecules is determined by F.P.L.C (Fast Protein Liquid Chromotography) chromatography; by using a standard filtration column and calibrated with known markers of molar mass such as cytochrome C, 12500 Da, alcohol deshydrogenase, 15000 Da, carboxylic anhydrase, 29000 Da, bovine albumine, 66000 Da, apoferritine, 443000 Da, thyroglobuline, 669000 Da; the detection of the eluted components is carried out by ultra-violet at 280 nm; a specific percentage of the proteins contained in each fraction, fraction F1 = molar mass over to 500,000 Da, fraction F2 = molar mass between 150,000 and 500,000 Da and fraction F3 = molar mass inferior to 150,000 Da, preferably this percentage is about 30% to about 60% in fraction F1, in particular from about 40% to about 50%. The percentage of proteins in fraction F1 is from about 15% to about 35%, in particular from about 20% to about 25%. The percentage of proteins in fraction F2 is from about 15% to about 45%, in particular from about 20% to about 40%, of particular interest are polymerized wheat proteins wherein the percentage of proteins in fraction F1 is about 45% (+/- 5%), in fraction F2 is about 30% (+/- 5%) and in fraction F3 is about 25% (+/- 5%).

A particularly preferred polymerized wheat protein is available under the trade name 'Polymère de Blé' from the company Silab (France).

Figure 1 represents a chromotographical profile of the polymerized wheat protein 'Polymère de Blé'.

The compositions of the present invention contain an ethanolamine of formula (I) as defined above. As used herein $C_{3-6}$ cycloalkyl refers to a cyclic cycloalkyl radical having from 3 to 6 carbon atoms and that preferably is saturated such as cyclopropyl, cyclobutyl, cyclopentyl and cyclohexyl. $C_{1-6}$ alkyl refers to straight and branch chained hydrocarbon radicals which preferably are saturated and have from 1 to 6 carbon atoms such as, for example, methyl, ethyl, n.propyl, iso-propyl, n.butyl, iso-butyl, t.butyl, n. pentyl, iso-pentyl, 2-methylbutyl, 2,2-dimethylpropyl, n-hexyl, 2-methylpentyl, 2,2-dimethylbutyl and the like. $C_{1-4}$ alkyl refers to the same group of radicals having 1 to 4 carbon atoms.

A particularly preferred ethanolamine of formula (I) is DMAE (deanol).

The ethanolamines of formula (I) can be prepared according to art-known procedures, e.g. by alkylating ethanolamine.

The ethanolamines of formula (I) can be used in their basic form or can be used as appropriate topically acceptable salts, the latter referring to acid-addition salt forms that are biologically acceptable for the skin and/or mucous membranes. Biologically acceptable in particular refers to lack of toxicity and of adverse effects such as irritation, allergic reactions and the like.

Suitable topically acceptable salts are those that are obtained by treating the base form of the ethanolamine of formula (I) with an appropriate acid. Suitable acids for use in the preparation of the ethanolamine salts according to the invention include any inorganic or, which is preferred, organic acid known to be useful in skin care compositions. These include acids such as, for example, inorganic acids such as hydrohalic acids, e.g. hydrochloric or hydrobromic acid; boric, sulfuric, nitric,

phosphoric and the like acids; or organic acids such as, for example, acetic, propanoic, hydroxyacetic (or glycolic), lactic, pyruvic, oxalic, malonic, succinic, maleic, fumaric, malic, tartaric, citric, methanesulfonic, ethanesulfonic, benzenesulfonic, *p*-toluenesulfonic, cyclamic, salicylic, *p*-aminosalicylic, ascorbic and the like acids.

In a preferred embodiment, at least one of the acids is an alpha hydroxy acid, such as taught for example in U.S. Patent No. 5,856,357, the disclosure of which is hereby incorporated by reference. Particularly preferred is a mixture of at least two of glycolic acid, malic acid and citric acids. In a most preferred embodiment, the acid is a combination of glycolic acid and either malic or citric acid. In situations where pH stability is a particular concern, e.g., long term storage, a particularly preferred embodiment is when the acid is a mixture of citric and glycolic acid. Preferably, the ratio of malic or citric acid to glycolic acid ranges from about 1:1 to about 1:5, more preferably, from about 1:1 to about 1:3.

Another compound, which is advantageously present in the compositions or formulations of this invention is tyrosine. Tyrosine may be present in the compositions or formulations of this invention in the amount of from about 0.01 to about 5%, more preferably from about 0.04 to about 3% by weight and most preferably about 0.5% by weight, based on the total composition or formulation.

In general, the compositions of the present invention are prepared by mixing at least one polymerized wheat protein with at least one ethanolamine of formula (I) or a salt form thereof, and if desired by adding further ingredients. The polymerized wheat proteins preferably are formulated in an aqueous medium, optionally in the presence of suitable preservatives. The compositions of the present invention therefore are mostly of aqueous nature. They may be prepared by adding the aqueous formulations of polymerized wheat proteins to the ethanolamine of formula (I), or its salt form, or vice versa.

In the compositions of the present invention the w/w ratio of the ethanolamine (I) to the polymerized wheat proteins may vary but in particular is in the range of about 50 : 1 to about 1 : 1, in particular of about 20 : 1 to about 2 : 1, preferably from about 15 : 1 to

about 5 : 1, more preferably the w/w ratio is about 8 : 1 to 7 : 1 (ethanolamine : wheat proteins). In these ratios, the quantity of ethanolamine is that of ethanolamine free base, meaning that if salts are used the ratios need to be recalculated accordingly. Furthermore, the quantity of polymerized wheat protein referred to in this paragraph is that of dry material.

This invention further relates to topical formulations containing a composition as defined herein. Topical formulations comprise dermatological formulations (or topical pharmaceutical formulations), and cosmetic formulations. Said topical formulations may further contain other ingredients or additives used in dermatological or in cosmetic formulations, including other active ingredients. Examples of further ingredients or additives are surfactants, emulsifiers, consistency factors, conditioners, emollients, skin caring ingredients, moisturizers, thickeners, lubricants, fillers, binding agents, anti-oxidants, preservatives, active ingredients, in particular dermatologically active ingredients, fragrances and the like. Active ingredients as mentioned herein comprise, for example, anti-inflammatories, anti-bacterials, anti-fungals and the like agents. Of particular interest are any active ingredients suited for topical applications.

The topical formulations according to the invention can further include one or more of a variety of optional ingredients, such as coloring agents, opacifying agents and the like.

The ethanolamine and more specifically dimehylethanolamine may be used in the formulations for topical application at concentrations from about 0.01% to about 10%, preferably from about 0.1% to about 5%, more preferably from about 0.5% to about 5%.

The total amount of polymerized wheat proteins should be used in the formulations for topical application at concentrations which may vary between about 0.01 % to about 2%, preferably from about 0.05% to about 1%, more preferably from about 0.1% to about 0.5%. As used in this paragraph, the percentages of polymerized wheat proteins refer to dry material.

The formulations according to the present invention can be prepared by adding the appropriate ingredients to a composition of the invention, or vice versa by adding the composition to an appropriate cosmetic or dermatological formulation base. It is also possible to mix all the ingredients individually, i.e. without making a separate composition as defined herein.

The topical formulations according to the invention may be in the form of a solution, a hydrophilic lotion, an ointment, a cream or a gel. The formulations may also be, for example, in the form of oil-in-water, water-in-oil or multiple emulsions, foaming products or in liposome form.

Of particular interest are formulations based on oil-in-water emulsions. In the latter instance an oil phase, containing the oil-soluble components, is made separately which is added to any of the aqueous phases containing suitable emulsifiers. Preferably the first aqueous phase is made containing one or more suitable emulsifiers. The oil phase is made and added to the first phase while building an emulsion. Subsequently the second aqueous phase is added. In the instance where the first or oil phase contains solid or semi-solid components, it is recommendable to heat the phase or phases and to conduct the emulsifying process at elevated temperature.

The topical formulations according to the invention can further include one or more of a variety of additional ingredients commonly found in skin care compositions, such as for example, emollients, skin conditioning agents, emulsifying agents, humectants, preservatives, antioxidants, active ingredients, perfumes, chelating agents, dyes, opacifying agents, etc., provided that they are physically and chemically compatible with the other components of the composition. Notably useful is the incorporation of vitamin A and vitamin A derivatives, including but not restricted to retinol, retinyl palmitate, retinoic acid, retinal, and retinyl propionate.

Examples of other active agents which may be incorporated comprise anti-microbials, e.g. anti-bacterials and antifungals, anti-inflammatory agents, anti-irritating compounds, anti-itching agents, moisturising agents, skin caring ingredients, plant

extracts, vitamins, and the like. Also included are sunscreen actives, which may be inorganic or organic in nature.

Examples of suitable preservatives for use in the compositions or formulations of the invention include the $C_1$-$C_4$ alkyl parabens and phenoxyethanol. Generally, the preservative is present in an amount ranging from about 0.5 to about 2.0, preferably about 1.0 to about 1.5, weight percent based on the total composition. In a preferred embodiment, the preservative is a mixture of from about 0.2 to about 0.5 weight percent methylparaben, from about 0.2 to about 5.0 weight percent propylparaben and from about 0.05 to about 0.10 weight percent butylparaben.

Preferably, antioxidants should be present in the compositions or formulations according to the invention. Suitable antioxidants include butylated hydroxy toluene (BHT), ascorbyl palmitate, butylated hydroanisole (BHA), phenyl-α-naphthylamine, hydroquinone, propyl gallate, nordihydroquiaretic acid, vitamin E or derivatives of vitamin E, vitamin C and derivatives thereof, calcium pantothenic, green tea extracts and mixed polyphenols, and mixtures thereof of the above. When utilized the antioxidant can be present in an amount ranging from about 0.02 to about 0.5% by weight, more preferably from about 0.002 to about 0.1% by weight of the total composition.

Emollients which can be included in the compositions or formulations of the invention function by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin appearance. Typical emollients include fatty esters, fatty alcohols, mineral oil, polyether siloxane copolymers and the like. Examples of suitable emollients include, but are not limited to, polypropylene glycol ("PPG")-15 stearyl ether, PPG-10 cetyl ether, steareth-10, oleth-8, PPG-4 lauryl ether, vitamin E acetate, PEG-7 glyceryl cocoate, lanolin, cetyl alcohol, octyl hydroxystearate, dimethicone, and combinations thereof. Cetyl alcohol, octyl hydroxystearate, dimethicone, and combinations thereof are preferred. When utilized, the emollient can be present in an amount from about 0.01 to about 5, preferably from about 1 to about 4 percent by weight based on the total composition.

Polyhydric alcohols can be utilized as humectants in the compositions or formulations of the invention. The humectants aid in increasing the effectiveness of the emollient, reduce scaling, stimulate removal of built-up scale and improve skin feel. Suitable polyhydric alcohols include, but are not limited to, glycerol (also known as glycerine), polyalkylene glycols, alkylene polyols and their derivatives, including butylene glycol, propylene glycol, dipropylene glycol, polypropylene glycol, polyethylene glycol and derivatives thereof, sorbitol, hydroxypropyl sorbitol, hexylene glycol, 1,3-dibutylene glycol, 1,2,6,-hexanetriol, ethoxylated glycerol, propoxylated glycerol and mixtures thereof. Glycerine is preferred. When utilized, the humectant is present in an amount from about 0.1 to about 5, preferably from about 1 to about 3 percent by weight, based on the total weight of the composition.

All the topical formulations as described above can also be applied on the skin by means of wipes.

The compositions and topical formulations subject of the present invention are useful to combat or to treat the effects of skin aging. The effects of skin aging comprise those associated with the aging of the skin such as the appearance of fine lines, fine wrinkling, wrinkling, loss of skin firmness, skin tightening and suppleness. The compositions and formulations of the present invention additionally act beneficially on the mechanical properties of the epidermis, stimulate the proliferation of dermal cells and in particular the proliferation of fibroblasts, stimulate of collagen synthesis, have a positive effect on cell metabolism and on extracellular matrix synthesis in dermal fibroblasts. They moreover have a firming and tightening effect, provide a more youthful and smooth aspect of the skin, and have a positive effect on its general appearance, in particular of facial skin.

Additionally, certain ethanolamine derivatives and in particular DMAE, are known to have skin-lifting and skin tightening effects and therefore improve the appearance of the skin.

The polymerized wheat protein and the ethanolamines of formula (I) act synergistically in their skin-lifting capability and therefore the compositions and formulations of the

invention possess improved lifting capability. Moreover, quite unexpectedly it has been found that when using the compositions and formulations of the invention, the skin-lifting and skin-tightening effects are observed immediately and although the effect is immediate, it remains for a long period of time.

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More specifically the known effects of the ethanolamines and in particular of DMAE are amplified by the presence of the polymerized wheat proteins.

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## Examples

The following example is meant to illustrate the invention and not to limit it thereto.

| Ingredients | % (w/w) |
|---|---|
| Aqua | 84.90 |
| Sclerotium gum | 0.75 |
| Arachidyl alcohol<br>Behenyl Alcohol<br>Arachidyl glucoside | 1.00 |
| Caprylyl glycol | 0.50 |
| Glycerine | 2.00 |
| Methylparaben | 0.15 |
| Polymerized wheat protein (dry material) | 0.33 |
| Sodium Methyl Paraben/<br>Sodium Propyl Paraben/<br>Sodium Ethyl Paraben | 0.023 |
| Dimethicone | 2.00 |

| | |
|---|---|
| Cyclopentansiloxane | 2.00 |
| Ammonium Acryloyldimethyltaurate /VP Copolymer | 1.00 |
| Citric acid | 0.87 |
| Glycolic acid | 1.73 |
| Dimethyl MEA | 2.50 |
| Perfume | 0.25 |
| Total | 100.00 |

The ingredients are mixed in ingredient groups as listed above (each group being separated by a blanc in the above table). The polymerized wheat protein is used dissolved in a small quantity of water together with the Paraben mixture. Subsequently the groups are mixed together to the end group.

Claims

1. A composition comprising at least one ethanolamine derivative of formula (I), or a topically acceptable salt thereof:

(I),

wherein in formula (I) $R^1$ and $R^2$ independently represent hydrogen, $C_{3-6}$ cycloalkyl or $C_{1-6}$ alkyl, optionally substituted with hydroxy, methoxy, oxo or formy, and at least a polymerized wheat protein.

2. A composition according to claim 1 wherein $R^1$ and $R^2$ independently represent $C_{1-4}$ alkyl.

3. A composition according to claim 1 or 2 wherein the ethanolamine of formula (I) is dimethylaminoethanol (DMAE).

4. A composition according to any of claims 1 - 3 wherein the ethanolamine of formula (I) is present as a glycolate or citrate or mixed glycolate/citrate salt form.

5. A composition according to claims 1 to 4 wherein the polymerized wheat protein is obtainable by a process comprising the following steps:

(a) solubilizing in an aqueous phase a material which is rich in wheat proteins;
(b) hydrolyzing by enzymatic reaction in a controlled and limited manner the solution of 1) wherein the level of enzymatic hydrolysis is selected such that monomeric proteins with a molar mass between 20,000 Da and 300,000 Da are obtained;
(c) separating the soluble phases from the insoluble phases;
(d) polymerizing the proteins by adding a suitable polymerizing agent.

6. A composition according to claim 5 wherein the polymerized wheat protein has a molecular distribution such that the fraction having a molar mass over 500,000 Da is present in an amount which is in the range of about 30% to about 60% (weight %).

7. A topical formulation comprising a composition as claimed in claims 1-6 and further ingredients.

8. Use of a composition as claimed in claims 1-6 for manufacturing a topical or in particular a cosmetic formulation.

9. Use of a composition as claimed in claims 1-6 or of a formulation as claimed in claim 7 for combating or treating the effects associated with the aging of skin.

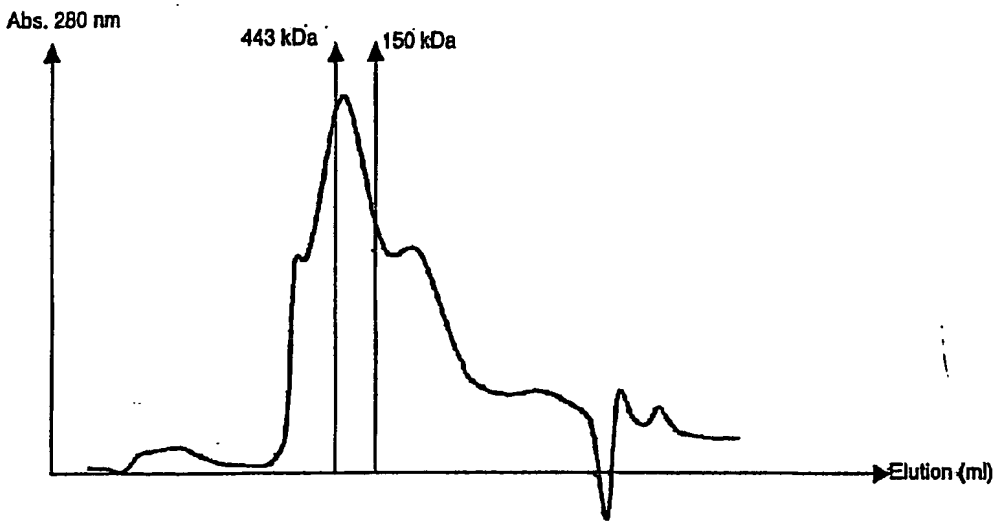


Fig. 1